IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,
Plaintiff,

v. CIVIL ACTION NO. 3:17-01362

AMERISOURCEBERGEN
DRUG CORPORATION, et al.,
Defendants.

CABELL COUNTY COMMISSION,
Plaintiff,

v. CIVIL ACTION NO. 3:17-01665

AMERISOURCEBERGEN
DRUG CORPORATION, et al.,
Defendants.

AMERISOURCEBERGEN DRUG CORPORATION'S REPLY MEMORANDUM IN SUPPORT OF MOTION FOR JUDGMENT UNDER RULE 52(c) BASED ON PLAINTIFFS' FAILURE TO PROVE CULPABLE CONDUCT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

PRELIMINARY STATEMENT

In its opening brief, AmerisourceBergen Drug Corporation (ABDC) explained that judgment should be entered in its favor pursuant to Rule 52(c) because of Plaintiffs' complete failure of proof on an essential element of a public nuisance claim—namely, that ABDC engaged in actionable conduct.[1] Plaintiffs have offered no evidence of wrongful conduct on the part of ABDC in Cabell County or the City of Huntington. Nor is there any evidence supporting Plaintiffs' fallback position claiming that there was some sort of system-wide failure of ABDC's diversion control program. The arguments ABDC made in its opening brief were moored to the evidence, pointing out both the evidence Plaintiffs lack and the affirmative evidence (including evidence from Plaintiffs' own witnesses) that undercut Plaintiffs' case.

Plaintiffs' response brief does nothing to call into question the conclusion that Plaintiffs have not satisfied their burden of proving wrongful conduct on the part of ABDC and that ABDC is entitled to judgment on partial findings under Rule 52(c). Much like Plaintiffs' presentation at trial, Plaintiffs' brief is replete with rhetoric, unfounded inferences, speculation, and lawyer argument. It is long on assertions, but short on actual evidence to back up those assertions. Some assertions lack any record citation at all. Others are not supported by the record citations provided.

Plaintiffs say that ABDC's diversion control systems are flawed—but they have ***no evidence*** of any such flaws. Indeed, the evidence relating to ABDC programs entirely belies Plaintiffs' system-wide failure theory—showing instead that ABDC's programs were approved, endorsed, and even touted by the Drug Enforcement Administration (DEA). Plaintiffs then try to

[1] ABDC also filed, together with the other Defendants, motions for judgment pursuant to Rule 52(c) based on Plaintiffs' failure to prove proximate cause and failure to prove entitlement to the "abatement" remedy they seek. ABDC has filed, together with the other Defendants, replies in further support of these motions.

pivot and say that the fact of diversion is some sort of circumstantial evidence of system-wide flaws. But that theory fails from the very start because there is no evidence at all of diversion of the opioid medications ABDC distributed to customers in Cabell or Huntington (or anywhere for that matter). Plaintiffs also try to find refuge in their well-worn but unsupported theme that the volume of opioid medication shipped into Cabell and Huntington somehow demonstrates flaws in ABDC's system. But Plaintiffs' volume theory of liability fails in every respect—indeed, it is undermined by the uncontroverted evidence coming from Plaintiffs' own witnesses and documents.

Plaintiffs, not surprisingly, have nothing at all to say in response to the evidence showing that the volume of pills distributed mirrors prescribing and that distributors cannot and should second-guess prescribing. Yet, Plaintiffs still say that Defendants should have "pulled the alarm" when they saw the increasing volume of pills ordered by Cabell and Huntington customers. But that is just lawyer argument that not only lacks evidentiary support, but also is contradicted by the record evidence. Plaintiffs' volume argument also is filled with gaps and fails as a matter of logic as well. For instance, Plaintiffs do not say what volume of pills was the right volume or what volume should have caused Defendants to "pull the alarm" and why that is so. Nor do Plaintiffs say what sort of alarm should have been pulled—that is, what they believe Defendants should have done.

Plaintiffs likely have nothing to say because there are no good answer to those questions and surely not answers supported by evidence. For instance, DEA had information about the aggregate number of pill shipped down to the zip code level, and it never pulled any sort of alarm as to Cabell and Huntington. Plaintiffs presumably think they know better than DEA and want to second-guess the DEA's judgment and impose liability on ABDC for failing to do something DEA

never did. Worse still, if Plaintiffs are suggesting that ABDC should have "pulled the alarm" by declining to ship some undefined and arbitrary number of pills as a means to reduce the total volume shipped to Cabell and Huntington, that too is problematic because patients would not have gotten needed medicines.

In fact, Mr. Rannazzisi's testimony about DEA's approach to quota-setting perfectly illustrates the problems with Plaintiffs "did-not-pull-the-alarm" liability theory. If distributors arbitrarily limit the supply of opioid medication, people will not get the prescription medication they need. And again, Plaintiffs never identify the "right" amount of opioid medication that should have been shipped. It surely cannot be 10 percent of the orders, as Mr. Rafalski suggests. And if distributors reduced their shipments by, say, a half, a third, or even a quarter, there is no way to know or control who would have access to that limited supply and who would be left empty-handed. These are the precise concerns Mr. Rannazzisi articulated when explaining why quotas increased during his tenure with DEA in the midst of the opioid crisis. Yet, Plaintiffs seem to believe that Defendants should have simply made arbitrary cuts to the supply even though doing so would cause harm. That also would contravene Congress' determination that controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people," 21 U.S.C. § 801(1), and Congress' judgment that the Controlled Substances Act (CSA) should be designed not only to "prevent the[] misuse" of controlled substances, but also to "foster the beneficial use of those medications." *Gonzalez v. Raich*, 545 U.S. 1, 24 (2005).

Because Plaintiffs have no evidence of wrongful conduct on the part of ABDC, judgment in ABDC's favor is required on that basis alone. *See* Section I, *infra*. But there is another independent and equally dispositive legal reason why judgment should be entered for ABDC (and

the other Defendants): Plaintiffs' wrongful conduct theory—which turns on alleged violations of the CSA—is foreclosed as a matter of law. Because a state law claim based on violations of a federal statute "is in essence a suit to enforce the statute itself," allowing such a claim would authorize private enforcement of the statute which Congress determined may not be privately enforced, which, in turn would contravene Congress's judgments and directives. *See Astra USA, Inc. v. Santa Clara County,* 563 U.S. 110, 118 (2011). When Congress determines that a federal statute should be enforced only by a federal government agency and not through civil lawsuits, the goal is to ensure that the federal statutory scheme is administered "harmoniously and on a uniform national basis" and not through a "multitude of dispersed and uncoordinated lawsuits." *Id.* at 120. This lawsuit—more specifically, Plaintiffs liability theory—is precisely what Congress sought to avoid and Supreme Court precedent forbids. *See* Section II, *infra*.

ARGUMENT

I. Plaintiffs Have Not Proved Wrongful Conduct

There is no evidence that ABDC engaged in actionable conduct in Cabell County or the City of Huntington. *See* Section A, *infra*. Nor is there any evidence to support Plaintiffs' contention that there were system-wide problems with ABDC's diversion control programs. *See* Section B, *infra*

A. There Is No Evidence Of Wrongful Conduct In Cabell Or Huntington

1. Plaintiffs' Opposition Does Not Point To Any Evidence Of Actionable Conduct Or Diversion

As ABDC explained in its opening brief, there is no evidence whatsoever that ABDC ever: failed to conduct adequate due diligence on its customers in Cabell and Huntington; failed to report a suspicious order made by a Cabell or Huntington customer; shipped a suspicious order to a Cabell or Huntington pharmacy; shipped controlled substances to a Cabell or Huntington pharmacy that

was not registered with the DEA; shipped controlled substances to a Cabell or Huntington DEA-registered pharmacy that the DEA had warned ABDC not to supply; or shipped a controlled substance into Cabell or Huntington that was diverted.[2] Plaintiffs' opposition does nothing to address these holes in their case.

Plaintiffs' liability theory is that Defendants caused a public nuisance by shipping to Cabell and Huntington too many prescription opioids, which, in turn, were improperly diverted. But there was an entire failure of proof on this point. Plaintiffs' witnesses did not establish diversion attributable to ABDC's shipments, let alone any diversion at all—indeed, they conceded they could not.[3] And, not surprisingly, Plaintiffs' opposition does not point to any evidence of diversion of prescription opioids ABDC shipped to Cabell and Huntington customers. Instead, Plaintiffs make a lawyer argument based on Mr. Rafalski's testimony that orders "ABDC knew or should have known were suspicious were likely to be diverted into Cabell-Huntington."[4] But, as Plaintiffs have conceded, Mr. Rafalski did not identify any orders that were actually diverted.[5] Because Plaintiffs did not prove diversion in Cabell and Huntington—let alone diversion attributable to ABDC's conduct, Plaintiffs have not proven that ABDC's conduct caused any harm in Cabell or Huntington.

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[2] *See, e.g.*, AmerisourceBergen Drug Corp.'s Memo. In Support Of Mot. For J. Under Rule 52(c) Based On Pl.s' Failure To Prove Culpable Conduct (ABDC Mov. Br.), Dkt. 1443, at 8 (citing record evidence).

[3] *See* ABDC Mov. Br. at 37 n.164.

[4] Pl.s' Resp. To AmerisourceBergen Drug Corp.'s Memo. In Support Of Mot. For J. Under Rule 52(c) Based On Pl.s' Failure To Prove Culpable Conduct (Pl.'s Opp.to ABDC Br.), Dkt. 1472, at 51.

[5] Dkt. 1472 at 34 ("Mr. Rafalski is not expressing an opinion on the number of suspicious orders that were actually diverted.").

2. Plaintiffs' Argument That ABDC Failed To Conduct Adequate Due Diligence Of Its Customers Misstates And Ignores The Evidentiary Record

Contrary to Plaintiffs' bald assertions, there is no evidence whatsoever that ABDC ever failed to conduct adequate due diligence on its customers in Cabell and Huntington,[6] let alone anywhere. Indeed, Plaintiffs' contention that ABDC failed to conduct adequate due diligence is devoid of any evidentiary support and ignores the extensive evidence regarding ABDC's due diligence program.

The evidence shows that ABDC conducted due diligence on its customers nationwide and in Cabell and Huntington. The ABDC witnesses whom Plaintiffs called in their case-in-chief described ABDC's customer due diligence program, how the program evolved over the years, and provided testimony specific to customers in Cabell and Huntington. Mr. Mays provided detailed and extensive testimony on the investigations ABDC conducted between October 2005 and August 2007—a program ABDC put in place after the 2005 distributor initiative meeting.[7] As part of that program, ABDC investigators validated and analyzed customers' one-year controlled substance purchase reports, site visit results, photos, Form 590 Questionnaires, and publicly available documents.[8] Mr. Mays further testified regarding the new program developed in 2007 with input from the DEA.[9] Mr. Zimmerman similarly explained the improvements ABDC made to its due diligence program in 2005 and 2007, as well as ABDC's due diligence policies and procedures generally.[10] Mr. May explained ABDC's customer due diligence, including its use of Tableau files

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[6] *See generally* 6/8 Tr. at 72:6-10, 83:23-84:14 (Rannazzisi).

[7] 5/18 Tr. at 202:20-205:23 (Mays).

[8] *Id.*; AM-WV-01079.

[9] 5/19 Tr. at 29:3-32:22 (Mays).

[10] 5/13 Tr. at 189:23-190:13 (Zimmerman) (improvements made in 2005); 194:2-12 (enhancements made in 2007).

to track and analyze all available data regarding every individual customer who purchased controlled substances, as well as nationwide trends.[11] And Mr. Perry testified about the training he received relating to "red flags," how he applied that training in the field, and then provided first hand observations of the three pharmacies Plaintiffs focus on in their response.[12] None of this testimony was refuted or challenged.

ABDC also introduced due diligence records regarding the three customers that are the focus of Plaintiffs' response. These documents conclusively refute Plaintiffs' unsupported assertions that ABDC did not conduct sufficient due diligence on Safescript #6 and did not have due diligence files for Drug Emporium and McCloud Family Pharmacy.[13]

Safescript. Plaintiffs point to Safescript #6 as supposed support of their contention that ABDC did not conduct sufficient due diligence on local pharmacies. The evidence, however, shows that ABDC ***did*** conduct due diligence on Safescript and also investigated the pharmacy.[14] The investigation was a proactive measure. ABDC's Corporate Security Regulatory Affairs (CSRA) personnel opened the investigation following their ***own*** review of Safescript's hydrocodone purchases in April 2007.[15] Mr. Perry, the local account manager, provided a CSRA Form 590 and photographs to ABDC's compliance personnel, and also provided compliance personnel with a detailed description of Safescript.[16] CSRA personnel then evaluated the due

[11] *See, e.g.*, 5/17 Tr. at 28:16-29:1; 50:10-55:11; 58:8-63:22; 65:8-68:13; 93:25-94:17 (May).

[12] 5/19 Tr. at 179:22-181:17 (Perry) (diversion training); 182:23-18:18 (Perry) (Safescript #6); 189:23-192:13 (Perry) (McCloud Family Pharmacy); 192:18-194:23 (Perry) (Drug Emporium).

[13] *See* AM-WV-01418 and AM-WV-01444 (Safescript); AM-WV-01410 (Drug Emporium); AM-WV-01999 (McCloud Family Pharmacy); and AM-WV-01040E (Drug Emporium and McCloud Family Pharmacy).

[14] AM-WV-01418; AM-WV-01444.

[15] AM-WV-01418; AM-WV-01444.

[16] AM-WV-01444.

diligence Mr. Perry collected along with its independent online research on Safescript, and concluded that Safescript "did not indicate any type of diversion."[17]

The trial record also includes evidence of ABDC's ongoing due diligence of every one of its customers that purchased controlled substances—including Safescript.[18] As Mr. May testified, since approximately 2009, ABDC's ongoing customer due diligence efforts generated monthly trend reports containing a list of all customers purchasing controlled substances and data points that the diversion control team used to track and review controlled substance purchasing.[19] This suite of reports included both the Order Monitoring Program (OMP) size report and product specific drug trend reports.[20] The OMP size report compared each customer's purchase of controlled substances to its purchase of all products and identified the percentage of controlled substances purchased by that customer over time.[21] The drug trend reports identified each customer's month over month controlled substance purchases for specific products like oxycodone and hydrocodone and also provided a monthly average for the five to six month time period covered by each report.[22]

In addition, Mr. Perry—the only trial witness who actually visited Safescript—provided a first-hand account on the pharmacy. He described Safescript as a "normal practice," which had a

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[17] *Id.*

[18] Contrary to Plaintiffs' contention that ABDC's discovery responses regarding Safescript due diligence "only consisted of several pages," ABDC's due diligence file for Safescript identifies more that 500 documents from ABDC's monthly suite of ongoing customer due diligence files discussed above covering the time period of December 2008 to February 2012 and pertaining to Safescript. *See* P-23655 at 371-86.

[19] 5/17 Tr. at 96:15-24; 101:7-16 (May).

[20] *See* AM-WV-00406; AM-WV-00398.

[21] *See* AM-WV-00406; 5/17 Tr. at 96:1-8 (May).

[22] *See* AM-WV-00398; 5/17 Tr. at 100:10-20 (May).

full line of pharmaceuticals on their shelves[23] and was located in an "okay" part of Huntington.[24] Mr. Perry further testified that Safescript was licensed by both the DEA and the West Virginia Board of Pharmacy.[25] And Mr. Perry, who visited Safescript approximately every other week for a period of several years, testified that he did not observe any red flags there.[26] Plaintiffs offered nothing that contradicted this testimony.

Plaintiffs' assertion that ABDC raised Safescript's thresholds without performing any due diligence thus is entirely unsupported and, in fact, is contradicted by the evidence. With the information obtained from their 2007 investigation, monthly trend reports and other ongoing due diligence efforts, and Mr. Perry's first-hand accounts in hand, ABDC adjusted Safescript's threshold both up and down over the years in response to the pharmacy's needs.[27] While Plaintiffs take issue with an oxycodone threshold increase in 2011, their own expert Dr. Craig McCann noted that oxycodone purchasing actually dropped after the threshold increase.[28] And Dr. McCann even testified that ABDC's email "seems to have been effective" in lowering Safescript's purchasing.[29] And ABDC was not the only one who knew about Safescript's purchases. ABDC reported to the DEA suspicious orders placed by Safescript every year from 2007 to 2011—the same period of time during which thresholds were adjusted.[30]

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[23] 5/19 Tr. at 184:19-185:1 (Perry).

[24] 5/19 Tr. at 185:2-8 (Perry).

[25] 5/19 Tr. at 185:9-18 (Perry).

[26] 5/19 Tr. at 185:19-187:18 (Perry).

[27] *See* 5/18 Tr. at 86:15-22 (Mays); s*ee also* AM-WV-01444; AM-WV-00406; AM-WV-00398.

[28] 5/11 Tr. at 90:21-91:2 (McCann).

[29] *Id*.

[30] *See* P-44766.

Drug Emporium and McCloud Family Pharmacy. Plaintiffs attack ABDC's due diligence on Drug Emporium and McCloud Family Pharmacy—suggesting that no due diligence was done. Plaintiffs try to support that assertion by pointing to a September 2015 internal email regarding records on these pharmacies. As a threshold matter, Plaintiffs misconstrue the email—it does ***not*** say that no due diligence was done or that no due diligence records existed.[31]

Moreover, the record evidence belies Plaintiffs' assertion. ABDC introduced evidence of its due diligence on Drug Emporium and McCloud. ABDC opened investigations into both pharmacies in 2007.[32] Consistent with ABDC's customer investigation program discussed above, Mr. Perry obtained Form 590s and photographs and submitted them to CSRA personnel.[33] Mr. Perry testified that he did not observe any "red flags" during his frequent visits to these customers.[34] ABDC's investigations concluded that there was no indication of diversion occurring at either pharmacy.[35] In addition to records of investigations and monthly trend reports for McCloud and Drug Emporium, ABDC introduced evidence of customer-specific Tableau files for both Drug Emporium and McCloud (files that represented due diligence of these pharmacies from April 2015).[36] And, Plaintiffs offered absolutely no evidence of wrongdoing or diversion occurring at either of these pharmacies.

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[31] P-17140; 5/17 Tr. 172:8-173:9 (May).

[32] AM-WV-01410; AM-WV-01999.

[33] *Id*.

[34] 5/19 Tr. at 194:10-12 & 16-21 (Perry) (Drug Emporium); 191:17-192:13 (Perry) (McCloud Family Pharmacy).

[35] *Id*.

[36] AM-WV-01040E; *see also* 5/17 at 176:6-19 (Q. And, so, at this point in September of 2015, is it fair to say that those dashboards are available for both order review and on-going customer due diligence to your Diversion Control Team? A. I think that was -- I believe that was part of my testimony on Friday where we talked about what defines due diligence. And, and from my perspective what defines due diligence is not only these sorts of documents, but also the day in and day out ordering by the customer, the Order Monitoring Program, and those continuous due

3. The Volume Of Pills Shipped To Cabell And Huntington Does Not Prove Unreasonable Conduct

Plaintiffs persist in pressing their free-floating theory that the volume of FDA-approved prescription opioids ABDC shipped to its licensed customers in Cabell and Huntington was too high and therefore evidence of unreasonable conduct. This liability theory is entirely unfounded—Plaintiffs did not prove their oversupply allegations, and in fact, the overwhelming evidence undermines those allegations.

As ABDC explained in its opening brief, the uncontroverted evidence—including that introduced through Plaintiffs' own witnesses—establishes beyond doubt that (1) the supply of opioids is driven by demand and (2) prescribers, not distributors, drive demand.[37] And the evidence also is uncontroverted that distributors have no obligation to police prescribers and should not second-guess medical decisions made by licensed prescribers.[38]

There was no evidence that ABDC oversupplied Cabell County, the City of Huntington or any individual ABDC customer. As the Court is well aware, Plaintiffs' expert Dr. McCann analyzed the transactional data ABDC reported to the DEA's ARCOS database and testified regarding the quantity of prescription opioids ABDC shipped to its customers in Cabell and Huntington. Notably, Dr. McCann testified that he could not say how many prescription opioids should have been distributed to Cabell and Huntington, or whether the distribution charts he

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diligence efforts around those analytical reports which I would argue carry the most value because it shows the transactional history of the customer.") (May).

[37] *See, e.g.*, ABDC Mov. Br. at 36 (citing 5/26 Tr. at 242:6–20 (Rafalski) ("no other way" for distribution to increase than for doctors to prescribe more opioids); 5/11 Tr. at 134:24–135:3 (McCann) (prescribing and distribution volumes are "two sides of the same coin"); 6/9 Tr. at 190:8–13 (Rannazzisi) (opioid crisis "started with prescriptions")).

[38] 6/9 Tr. at 154:14-155:7 (Rannazzisi); *see also* 5/26 Tr. at 117:8-12 (Rafalski).

prepared and testified about at trial showed over-supply or under-supply.[39] Dr. McCann was not alone. Not a single witness testified regarding the supposed "proper" amount of prescription opioids ABDC should have shipped or even attempted to quantify the alleged oversupply.[40] On top of that, DEA, which had all the information on the number of prescription opioids distributed to these jurisdictions, never told distributors that too many pills were being shipped to Cabell or Huntington.[41] And, finally, not a single witness testified that the prescription opioids ABDC distributed to its licensed customers in Cabell and Huntington were used to fill anything other than legitimate prescriptions dispensed by those licensed customers.

Simply put, Plaintiffs did not prove oversupply to Cabell and Huntington customers—they just said there was. And this is not just a matter of the absence of evidence—instead, the evidence entirely undermines Plaintiffs' contention that ABDC engaged in unreasonable conduct by distributing too many prescription opioid pills to its licensed customers in Cabell and Huntington.

For instance, the evidence showed that that the volume of prescription opioids ABDC distributed to its licensed customers in Cabell and Huntington was the direct result of the prescriptions written by licensed doctors in Cabell and Huntington. Plaintiffs' witness Mr. Rannazzisi, former head of the DEA's Office of Diversion Control, testified succinctly that "supply does not drive demand"—instead, the demand for prescription opioids is the result of appropriate medical treatment.[42] Numerous witness—including Plaintiffs' witnesses—testified that the overwhelming majority of doctors were prescribing prescription opioids in good faith and

[39] 5/11 Tr. at 66:6-13 (McCann).

[40] *See, e.g.*, 6/15 Tr. at 168:11-17 (Keller).

[41] 6/9 Tr. at 94:10-15 (Rannazzisi).

[42] 6/9 Tr. at 87:23-89:13 (Rannazzisi). And this is why DEA repeatedly raised quotas for prescription opioids nationwide—in order to meet legitimate medical and scientific need. 6/8 Tr. at 199:2-203:18 (Rannazzisi); 6/9 Tr. at 87:7-11 (Rannazzisi).

in line with the then-standard of care.[43] Plaintiffs' witnesses also testified that the standard of care for treating pain in the United States changed in the early 2000s, and that doctors treated pain more aggressively through more liberal prescribing of prescription opioids.[44]

The relationship between prescribing and distribution was driven home by the testimony of Plaintiffs' experts showing the 1:1 relationship between the pattern of distribution of opioid pills into Cabell and Huntington and the pattern of prescriptions written by licensed physicians. The separate analysis of two of Plaintiffs' expert—Dr. McCann and Lacy Keller—confirmed that the volume of ABDC's distribution of prescription opioids to Cabell and Huntington was the direct result of doctor prescribing. Based on DEA's ARCOS data, Dr. McCann calculated the distribution numbers to Cabell and Huntington. Based on data purchased from IQVIA, Ms. Keller calculated prescribing numbers in Cabell and Huntington. The work of these Plaintiff-experts, who worked separately in two different databases, showed that the per capita distribution rates and per capita prescribing rates they calculated matched almost exactly.[45] Ms. Keller testified that increases and decreases in prescribing in Cabell and Huntington trended consistently with Dr. McCann's distribution figures, and that prescribing in Cabell and Huntington exceeded state and national figures. Thus, it is not surprising, and certainly not unreasonable, that ABDC distributed

[43] *See*, *e.g.*, 5/4 Tr. at 104:15-20 (Waller); 5/6 Tr. at 94:4-10 (Gupta); 5/26 Tr. at 121:13-19 (Rafalski); 6/9 Tr. at 100:6-10 (Rannazzisi); 6/14 Tr. at 71:3-7 (Keyes).

[44] *See*, *e.g.*, 5/21 Tr. at 27:13-16 (Werthammer); 6/16 Tr. at 182:16-20 (Yingling); 6/30 Tr. at 96:14-19 (Williams); 6/14 at 82:19-22 (Keyes); DEF-WV-00473 (email discussing the role doctors and Pain as the Fifth Vital Sign played in the opioid epidemic); DEF-WV-02124 (*City of Huntington v. JCAHO* Complaint).

[45] *Compare* 5/10 Tr. at 65:15-18 (McCann) (noting "on a per capita basis, the total across the 14 drugs is 142 dosage units per capita in the Cabell and Huntington City") *with* (6/15 Tr. at 214-14-18) (Keller looking at McCann's charts) and 142.19 (Keller calculating average number of pills per capita shipped into Cabell from 2006 to 2014).

more prescription opioids on average to its customers in Cabell and Huntington than some supposed state and national average calculated by Dr. McCann.[46]

The volume of prescription opioids distributed to Cabell and Huntington, therefore, does not establish wrongful conduct—far from it.

B. The Evidence Relating To ABDC's Diversion Control Program Does Not Establish Unreasonable Conduct

Given the complete failure of proof regarding any wrongful conduct in Cabell or Huntington, Plaintiffs resort to arguing that there were some sort of system-wide diversion control failures that amount to wrongful conduct. This liability theory fails too. Indeed, there is no evidence supporting Plaintiffs' assertion that there were systemic failures in ABDC's diversion control program, including its suspicious order monitoring programs.

ABDC's opening brief explained why Plaintiffs did not prove unreasonable conduct when it comes to ABDC's diversion control programs and that the evidence, in fact, showed exactly the opposite. In 1998, DEA granted express written approval of Bergen Brunswig's (ABDC's predecessor) nationwide SOM program after Bergen worked with DEA to build it. When DEA approved the program, it knew that orders identified as suspicious were shipped to customers and then reported to DEA in an excessive purchase report. Bergen Brunswig, and then ABDC, operated this DEA-approved SOM program on a nationwide basis until April 2007, when ABDC enhanced its SOM program, again with DEA's specific guidance. Indeed, DEA held out ABDC's 2007 program as a model for the industry to follow. There is no evidence to the contrary. The evidence

[46] While his testimony was not part of Plaintiffs' case, ABDC notes the testimony of Theodore Martens, retired PricewaterhouseCoopers partner, that ABDC's distribution of prescription opioids tracked its distributions of all medications generally. Mr. Martens' analysis and testimony is entirely consistent with the testimony of Plaintiffs' witnesses who testified that the City of Huntington is a regional healthcare hub, and that West Virginia leads the nation in prescription medications per person. *See* 6/16 Tr. at 201:18-22 (Yingling) and 5/6 Tr. at 32:3-33:9 (Gupta).

further shows that ABDC has continued to enhance its diversion control program in the following years. It enhanced its program in 2014, and it has done an annual "refresh" of its program every year since then to implement program adjustments and technological advancements, and DEA consistently held out ABDC's program to the industry as a model to be emulated. The evidence on this too is uncontroverted.[47]

The evidence also is uncontroverted that, with the exception of a brief shutdown of ABDC's Orlando, Florida facility 14 years ago—which related exclusively to four internet pharmacies in Florida that had no connection at all to West Virginia—DEA has never brought an enforcement action against ABDC. And while ABDC resolved the brief Orlando shutdown through an agreement with DEA, ABDC did not then admit, and has never admitted, to any wrongdoing and has never paid any fine to DEA. After that, there is ***absolutely nothing***—even Plaintiffs' witness Mr. Rannazzisi expressly said so. There is no evidence that DEA ever determined that ABDC engaged in conduct warranting an investigation or enforcement action.[48]

As shown below, Plaintiffs' opposition does not undermine any of this or otherwise point to evidence of system-wide failures.

1. The Evidence Clearly Established That DEA Approved ABDC's Pre-2007 Program

In the face of overwhelming evidence to the contrary, Plaintiffs contend that the DEA did not approve ABDC's 1998 suspicious order monitoring program.[49] Plaintiffs' sole support of that contention is their assertions that "DEA does not approve or endorse SOM systems" and if DEA

[47] *See* ABDC's Mov. Br. at 28-30.

[48] *See* ABDC Mov. Br. at 31-32.

[49] After the merger between Bergen Brunswig and Amerisource in 2001, the newly formed ABDC utilized the program developed by Bergen Brunswig until 2007. *See* ABDC Mov. Br. at 12.

approved anything, it was only the method of reporting via facsimile.[50] But the documentary evidence shows that that DEA ***did*** approve the 1998 program and that the approval was ***not*** just for the method of reporting.

The "evidence" Plaintiffs cite does not contradict the direct record evidence on this. Plaintiffs point to the testimony of Thomas Prevoznik and Joseph Rannazzisi stating generally that that DEA does not approve suspicious order monitoring systems.[51] But when confronted with the DEA's 1998 approval letter—which expressly says "subject: approve suspicious order monitoring system"[52]—both witnesses had no choice but to concede that the letter was an approval of a suspicious order monitoring system.[53]

This Court heard from only one witness with has first-hand knowledge of Bergen Brunswig's interactions with DEA between 1996 and 1998: Chris Zimmerman, Senior Vice-President of CSRA. Mr. Zimmerman's testimony was clear and uncontradicted: DEA ***did*** approve Bergen Brunswig's system and the approval was for the ***entire*** Bergen Brunswig suspicious order monitoring system.[54] And Mr. Zimmerman's testimony was confirmed by DEA's letter to Bergen

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[50] Pl.'s Opp. to ABDC Br. at 24-25.

[51] Pl.'s Opp. to ABDC Br. at 24.

[52] AM-WV-02658.

[53] *See* Prevoznik, 5/17/2019 Dep. at 1134:20-23, 1135:2-10 ("Q. Now, we've seen at least two responses from DEA about the program. They're approving a suspicious order monitoring system, right? THE WITNESS: They're approving the system -- they're approving the implementation of the system that Bergen Brunswig designed. That's what they're approving."); Prevoznik, 5/17/2019 Dep. at 1139:10-16 ("Q. Okay. Mr. Prevoznik, the DEA approved for implementation nationwide a suspicious order monitoring system that reported suspicious orders to the DEA on a daily basis after the report -- after the orders had already been shipped, correct? A. Yes."); 6/9 Tr. at 226:2-3 (Rannazzisi) ("Q. Well, on its face, it's an approval; correct? A. On its face, it looks like an approval."). Mike Mapes—a former DEA employee—also testified at deposition that DEA had approved suspicious order monitoring systems. *See* Mapes, 7/11/2019 Dep. at 97:25-98:4, 98:7-22, 98:24-99:13.

[54] *See* 5/13 Tr. at 180:6-8; 185:3-20; 186:4-21 (Zimmerman).

Brunswig in 1998, which was stamped with the phrase "subject: approve suspicious order monitoring system."[55]

Other record evidence contradicts Plaintiffs' assertion that the approval conferred in the 1998 letter was limited to approving the transmission of suspicious order reports by facsimile. Nowhere in the letter does DEA say that its approval was merely for the "method" of reporting only. To the contrary, DEA's 1998 approval letter explicitly stated that it was granting approval for Bergen's "newly developed ***system*** to ***identify and report*** suspicious orders for controlled substances and regulated chemicals, ***as required by Federal regulation***."[56] And the extensive correspondence also make clear that Bergen Brunswig designed the program with direct input from the DEA, including on the thresholds to be used.[57] Mr. Prevoznik confirmed this:

> Q. Okay. Based off of this document, Bergen Brunswig Drug Corporation developed this suspicious order reporting system in '96 to '98 with the DEA?
>
> THE WITNESS: From the various letters that you've given me, Bergen Brunswig came with a system that they wanted to show us, asked us for our input. So they showed us the design of what they were -- the design of the system that they were proposing to put nationwide. So we provided input. We tested it with them. So, yes.
>
> Q. Okay. And in designing it, the DEA provided input on the design, correct?
>
> A. Yes.
>
> Q. And the DEA tested the program, correct?
>
> THE WITNESS: Yes.

[55] AM-WV-02658.

[56] *Id.* (emphasis added).

[57] AM-WV-00781 at 11 (letter from C. Zimmerman to DEA in 1996 noting: "There are some key questions that DEA would need to provide input on before the report is finalized. One question would be the assignment of the percentage value that a customer's order would have to exceed before that order would appear on the report. ... *Working with DEA's input, we hopefully will identify the optimum percentage value that will yield DEA the highest quality information* ...." (emphasis added)).

> Q. And the DEA, based off of this document, was very pleased with how the suspicious order monitoring program was being run, correct?
>
> THE WITNESS: That's what it appears from the letter.[58]

Thus, Plaintiffs' contention that ABDC's 1998 suspicious order monitoring system was not approved by DEA is nothing more than lawyer argument that is unsupported—indeed, contradicted—by the record evidence.

2. ABDC's 2007 Program Was Compliant And DEA Held It Up As The Industry Standard

ABDC's opening brief explained in detail—with supporting evidence—that it worked with the DEA in 2007 to design a new suspicious order monitoring system and DEA tacitly approved that program.[59] Plaintiffs nonetheless claim that the 2007 program was "inadequate."[60]

This vague criticism is entirely unfounded—and, indeed, is contradicted by the evidence. DEA was aware of every aspect of this program including use of customer type, sizing, drug product families, peer groups, use of averages, and the multipliers (or thresholds) used, and had knowledge of the order monitoring process generally.[61] And ample record evidence—from multiple sources—shows DEA's endorsement of the program DEA. For instance, DEA asked ABDC to present the new program to the entire industry at a conference in September 2007 alongside DEA employee Mike Mapes.[62]

Mr. Mapes' testimony about this presentation was clear: DEA asked ABDC to present at this conference ***because*** ABDC's newly developed system was ***compliant with the CSA***:

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[58] Prevoznik, 5/17/2019 Dep. at 1127:13-16, 1127:19-1128:3, 1129:6-8, 1129:12-13, 1129:15-20, 1129:23-24 (emphasis added).

[59] *See* ABDC Mov. Br. at 20-25.

[60] Pl.'s Opp.to ABDC Br. at 4.

[61] 5/19/2021 Tr. (Mays) at 45:3-46:24.

[62] *See* ABDC Mov. Br. at 24; DEF-WV-02191 (DEA website).

> Q. Did you have an understanding that Chris Zimmerman was asked to present at this conference because you and DEA thought that AmerisourceBergen's new system, the changed system, was appropriate and would be good to share with others in the industry?
>
> THE WITNESS: Yes, that was my understanding of why he was asked to be part of that.
>
> . . .
>
> Q. Do you believe that -- was it your understanding that it was expected by DEA, to your understanding, to serve as a new standard?
>
> THE WITNESS: It's my understanding that the AmerisourceBergen system was an example of a system that contained the type of information that we were looking for.
>
> Q. And was compliant with the Controlled Substances Act?
>
> A. Yes.[63]

And a Cardinal representative who attended the conference said that "DEA referred to the ABC program as the new industry standard."[64] Then, DEA asked ABDC to present its program ***again*** to the industry at a conference in 2009.[65] A description of ABDC's 2007 presentation, as well as its participation in the 2009 DEA conference, are still on DEA's website to this very day.[66]

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[63] Mapes, 7/11/2019 Dep. at 178:11-16, 178:24-179:1; 181:24-182:2, 182:9-182:18.

[64] CAH-WV-00374; *see also* Reardon (of Cardinal), 11/30/2018 Dep. at 528:19-24 ("Q. Tell the jury what you remember about the (ABC) presentation. A. That essentially this was going to be the new standard for the industry with respect to how suspicious orders were monitored, reported and handled); CAH-WV-00372 (Cardinal representative's handwritten notes on presentation Chris Zimmerman gave to industry in 2007).

[65] ABDC Mov. Br. at 24-25; 5/13/2021 Tr. at 205:25-206:25 (Zimmerman); DEF-WV-00002.

[66] *See* Pharmaceutical Industry Conference, U.S. Department of Justice Drug Enforcement Administration Diversion Control Division, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html (last visited Aug. 11, 2021) (admitted at DEF-WV-02191); Pharmaceutical Industry Conference, U.S. Department of Justice Drug Enforcement Administration Diversion Control Division, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/index.html (last visited Aug. 11, 2021).

To the extent Plaintiffs are contending that ABDC did not operate its 2007 program as designed, that contention is undermined by yet other uncontradicted evidence. After Mr. Mapes' retirement from DEA in 2008, ABDC hired Mr. Mapes to audit its program.[67] On each audit, Mr. Mapes found that ABDC's program was "fully compliant and working as designed."[68] Therefore, any contention that ABDC's program was not operating as intended is just wrong.

3. Plaintiffs Offer No Evidence That ABDC's Thresholds Were "Inflated"

Searching for something specific about ABDC's programs to criticize, Plaintiffs assert that the thresholds utilized in both ABDC's 1998-2007 and 2007-2014 suspicious order monitoring programs were "inflated."[69] This vague assertion does not even come close to proving that ABDC engaged in wrongful conduct.[70]

To begin with, DEA knew the thresholds ABDC utilized in both programs. Mr. Zimmerman testified that he worked with DEA to set the thresholds in the 1998 program.[71] And the correspondence between Bergen Brunswig and DEA between 1996 and 1998 clearly shows that an understanding that DEA would provide input into the thresholds used.[72] As for the

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[67] 5/19 Tr. at 47:8-49:17 (Mays).

[68] 5/19 Tr. at 49:18-50:7 (Mays).

[69] *See* Pl.'s Opp.to ABDC Br. at 2-6.

[70] Plaintiffs' assertion that ABDC's thresholds "were further eroded by its practice of warning its pharmacy customers that they were approaching their monthly threshold" does not establish systemic failures. *Id.* at 5. As their sole support of this contention, Plaintiffs point to an excerpt from the deposition of a former ABDC employee relating to his discussions with Walgreens' internal diversion control team. *See* Pl. Opp to ABDC's Br. at 5 n.19. But Plaintiffs do not connect this discussion to any system-wide failure—for instance, they do not explain why it was in any way inappropriate or led to diversion.

[71] *See* 5/13 Tr. at 185:11-15 (Zimmerman) (noting that part of the program was that DEA could ***tailor*** the thresholds used if they wanted).

[72] AM-WV-00781 at 11 (1996 letter from Zimmerman to DEA noting that one outstanding question that "DEA would need to provide input on before the report is finalized" was "the

2007 program, Steve Mays, Vice-President of Regulatory Affairs, testified ABDC worked with DEA in designing the program and that DEA knew the multiplier ABDC would be using.[73] The evidence on each of these points in uncontroverted.

In the face of the evidence that that DEA knew and effectively blessed the thresholds ABDC used, Plaintiffs did not offer a single witness who told this Court what ABDC's thresholds ***should have been***. In fact, their own expert—in testimony that Plaintiffs themselves elicited—testified that there was not "one particular golden rule on what the trigger should be."[74]

4. ABDC Did Not Ignore DEA Guidance

a. The 2000 Memorandum Of Understanding Did Not Relate To Suspicious Order Monitoring

In a last-ditch effort to find something that might even remotely suggest wrongdoing by ABDC, Plaintiffs point to a 2000 Memorandum of Understanding (MOU) between AmerisourceHealth and the DEA.[75] Plaintiffs come up short again. The 2000 MOU has nothing whatsoever to do with ABDC's suspicious order monitoring program. Instead, it related only to ***physical security***—and there is no indication that whatever security measures were at issue

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assignment of the percentage value that a customer's order would have to exceed before that order would appear on the report").

[73] 5/19 Tr. at 45:16-46:8 (Mays). Further, the handwritten notes of Steve Reardon, Cardinal's representative at the 2007 industry conference, reveal that ABDC's use of a 3x multiplier was disclosed during Mr. Zimmerman's presentation—a presentation which included a DEA representative on stage with Mr. Zimmerman as this information was disclosed. *See* CAH-WV-00372 at 4 (handwritten notes from Mr. Reardon noting "6 months sales Avg x 3" when discussing "OMP Item Family and Threshold").

[74] 5/26 Tr. at 82:15-17 (Rafalski).

[75] *See* Pl.'s Opp.to ABDC Br. at 25. Plaintiffs offered no trial testimony on this document. Instead, it was submitted (as P-00324) together with the deposition designations of Eric Cherveny. ABDC has objected to the document on two grounds—lack foundation and hearsay. Mr. Cherveny, who did not even work for AmerisourceHealth in 2000, had no knowledge or recollection of this document. Thus, the documents not only is inadmissible, but it illuminates nothing. ABDC has responded on the merits without waiving its objections to the introduction of this document into evidence.

resulted in any diversion or any harm anywhere in the country (let alone in Cabell or Huntington).[76] And nothing in the MOU suggests that AmerisourceHealth was fined or required to change its suspicious order monitoring system in any way.[77]

b. ABDC Took Action After The 2005 Distributor Initiative, And Did Not Ignore Guidance DEA Provided

Plaintiffs' assertion that ABDC ignored information it obtained from the DEA at a meeting in 2005 is flat wrong. Steve Mays, who attended this meeting on behalf of ABDC, testified that ABDC adopted the pharmacy questionnaire DEA provided it at the meeting and began investigating hundreds of pharmacies.[78] His testimony was corroborated by documents showing that ABDC adopted a pharmacy questionnaire and conducted investigations, including investigations of 9 pharmacies in Cabell/Huntington.[79] Additionally, to the extent Plaintiffs suggest that DEA conveyed a "no shipping" requirement the 2005 meeting, there is absolutely no evidence to support that assertion. Mr. Mays' testimony was clear: the DEA did not tell ABDC to stop shipping suspicious orders at this meeting.[80] This testimony is uncontradicted. Indeed, DEA's own internal memo documenting what occurred at this meeting said nothing about stopping shipment of suspicious orders.[81] And Mr. Mapes, who attended the meeting and signed the memo, confirmed that anything discussed at the meeting would have been memorialized in the memo.[82]

With no evidence that ABDC ignored guidance from the 2005 meeting with DEA, Plaintiffs next turn to letters issued by DEA between 2006 and 2007. Plaintiffs' contention that ABDC

[76] P-00324 (citing various regulations that deal with security).
[77] *See id.*
[78] *See* 5/18 Tr. at 198:1-199:12 (Mays); 5/19 Tr. at 8:1-7 (Mays).
[79] *See* AM-WV-01079; AM-WV-00714A; *see also* ABDC Mov. Br. at 14-18.
[80] 5/18 Tr. at 199:21-24 (Mays).
[81] P-09112.
[82] Mapes, 7/11/2019 Dep. at 140:21-25, 141:1-9.

ignored these letters turns principally on the December 27, 2007 letter.[83] But, by the time this letter was issued, ABDC already had changed its suspicious order monitoring program and it aligned with the guidance in the 2007 letter.[84]

c. The 2007 ISO Does Not Indicate ABDC's Suspicious Order Monitoring System Was Inadequate

Plaintiffs also point to the 2007 ISO as evidence of wrongdoing on the part of ABDC. But the ISO does not support their sweeping public nuisance claim—which tries to lay blame on ABDC for what they say is a $2 billion-plus opioid crisis in Cabell and Huntington—either.

To begin with, Plaintiffs simply ignore that the uncontroverted fact that ABDC paid ***no*** fine and explicitly stated that it expressly denied the allegations in the ISO relating to its Orlando, Florida distribution center,[85] which came without any warning.[86] In fact, ABDC has ***never*** paid a fine to the DEA.[87] And according to Mr. Rannazzisi, who was the head of DEA until 2015, ABDC did not even "come up" again after 2007.[88]

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[83] *See* P-00032 at 3.

[84] *See* ABDC Mov. Br. at 17-18 n.65; *id.* at 19-20. Further, Plaintiffs' assertion that Mr. Zimmerman did not "communicate his disagreement with the [December 27, 2007] Rannazzisi letter during his frequent discussions with the DEA in resolving an ISO in 2007" makes little sense. *See* Pl.'s Opp. to ABDC Br. at 32 n.163. Mr. Zimmerman's conversations with the DEA relating to ABDC's ISO took place between April and June 2007, when a settlement was executed between the parties. This was long before the December letter was sent, and as such Mr. Zimmerman would not have had an opportunity—in June 2007—to ask DEA about a letter that was not sent until December 2007.

[85] The ISO related to four internet pharmacies, three of which ABDC has already cut off before DEA issued the ISO. *See* 5/13 Tr. at 192:12-21 (Zimmerman).

[86] *See* ABDC Mov. Br. at 20, 23.

[87] 6/10 Tr. at 24:13-16 (Rannazzisi).

[88] ABDC Mov. Br. at 4; *see also* 6/8 Tr. at 72:6-19 (Rannazzisi).

Moreover, the only distribution center that was the subject of this ISO was ABDC's Orlando, Florida location,[89] which did ***not*** ship to Cabell and Huntington.[90] In an effort to avoid these facts, Plaintiffs state that internet pharmacies "shipped opioids to any location" and "would have provided opioids across the United States, including West Virginia," implying that the four internet pharmacies that were the subject of this ISO shipped opioids to West Virginia.[91] That is false. There is absolutely no evidence that a single pill shipped by any of the four internet pharmacies that were the subject of the 2007 ISO made their way into West Virginia, let alone into Cabell or Huntington. Plaintiffs' only supposed support for their contention is Mr. Rannazzisi's testimony that internet pharmacies shipped opioids across the country—but there is no ***evidence*** that any of the internet pharmacies that were the subject of the ISO shipped to West Virginia.

5. The FTI Report Does Not Support Plaintiffs' System-Wide Failure Contention

Plaintiffs claim that the FTI Consulting report related exclusively to ABDC's order monitoring program and then make baseless assertions about what the document means divorced from the evidence introduced at trial. For starters, Plaintiffs entirely ignore David May's trial testimony about the FTI report and ABDC's response to it. They claim that ABDC did nothing in in response to FTI's findings and even go so far as to say the FTI report is evidence that ABDC lacked "legitimate guardrails to reign in the volume of opioids it continued to dump into communities across the country."[92] Neither assertion is true. ABDC did respond to the FTI report.

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[89] 6/10 Tr. at 22:22-24 (Rannazzisi).

[90] *See* 5/12/Tr. at 149:23-150:2 (Zimmerman) (testifying that the Lockbourne distribution center ships to Cabell and Huntington); *see also* P-44711 at 28 (showing the ABDC distribution centers that serviced Cabell and Huntington with ***any*** prescription opioids between 2002 and 2018 were Lockbourne, Ohio, Antioch, Tennessee, and North Amityville, New York).

[91] *See* Pl.'s Opp.to ABDC Br. at 34.

[92] Pl.'s Opp.to ABDC Br. at 36.

And the report is not evidence of any lack of guardrails. To the contrary, the FTI report is evidence of ABDC's proactive efforts to review its own processes, identify any potential areas for improvement, and implement enhancements to its programs where necessary.

As the report itself notes, ABDC's diversion control team was already in the process of implementing a number of enhancements to its order monitoring program and, as a result, the report's commentary on diversion control was limited to "a couple of key observations and risk areas."[93] The vast majority of the report reviews other aspects of ABDC's compliance program that are unrelated to diversion control.[94] Those key observations do not support Plaintiffs' claims of inadequacies, shortfalls, and lack of legitimate guardrails to dump opioids into communities across the country.

And, contrary to Plaintiffs' assertions, ABDC did not ignore the FTI report. Instead, the evidence shows that it reviewed the report, took it seriously, and developed a response to the observations offered.[95] For instance, Mr. May prepared a response regarding the report's observations on diversion control observations.[96] While Mr. May testified that he disagreed with several of FTI's observations, the evidence clearly identifies recommendations that ADBC's CSRA department sought to implement following the report.[97]

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[93] *See* P-00093 at 10-11; *see also* 5/17 Tr. at 115:11-116:2 (May).

[94] *See* P-00093 at 6.

[95] 5/17 Tr. at 112:16-18; 114:13-115:20 (May).

[96] *See* P-00472.

[97] 5/17 Tr. at 114:13-115:7 (May); *see also* P-00472 at 3.

6. ABDC's Form 590 Validation Project Does Not Prove Systemic Failures

Plaintiffs also resort to an attack on ABDC's Form 590 validation project, which was a company initiative launched in 2016 to validate and update customer Form 590 information.[98] This effort gets Plaintiffs no farther. ABDC not only presented evidence that it obtained Form 590s from Safescript, McCloud, and Drug Emporium, but the evidence also shows that ABDC obtained Form 590 information for customer after customer in Cabell and Huntington.[99] ABDC expanded the use of the Form 590 in 2007 as part of enhancements to its diversion control program and required that all new pharmacy customers, except for chain customers, submit a Form 590.[100] Notably, even though chain customers were not required to submit a Form 590 until a later date, when ABDC investigated Cabell and Huntington chain customer Fruth in 2007, it obtained a Form 590.[101] Moreover, Plaintiffs' focus on the Form 590 completely ignores the evidence about ABDC's monthly trend reports and Tableau files discussed at length above.

Because Plaintiffs fail to address the ongoing customer due diligence aspect of ABDC's diversion control program, Plaintiffs' contentions about ABDC's due diligence ring hollow.

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[98] Pl.'s Opp. to ABDC Br. at 10-11.

[99] *See* AM-WV-01444 (Safescript #6 – "The Account Manager, Michael Perry, forwarded the CSRA Form 590 and photographs."); AM-WV-01406 (Fruth – "The Account Manager, Michael Perry, forwarded me the CSRA Form 590 and photographs."); AM-WV-01410 (Drug Emporium – "Account Manager Michael Perry completed CSRA Form 590 and sent photographs of the establishment."); AM-WV-01409 (Budget Discount Pharmacy – "Account Manager Mike Perry completed CSRA Form 590c and forwarded hard copies of the required photographs."); AM-WV-01416 (Medicap Pharmacy – "The Account Manager, Michael Perry, forwarded the CSRA Form 590 and photographs."); AM-WV-01415 (Medical Park Pharmacy – "Don forwarded me the CSRA Form 590 and photographs, which are included in the file."); AM-WV-01999 (McCloud Family Pharmacy – "The Account Manager, Michael Perry, forwarded the CSRA Form 590 and photographs.")

[100] *See* DEF-WV-02191 at 2 (DEA website); 5/19 Tr. at 38:13-18 (Mays).

[101] *See* AM-WV-01406.

ABDC conducted extensive due diligence on its customers—including those in Cabell and Huntington—and Plaintiffs' assertion that ABDC did not follow its policies is contradicted by the evidence.

Plaintiffs' attack on ABDC's use of sales personnel to collect customer information also falls flat. It completely ignores Mr. Perry's testimony that ABDC's ***CSRA personnel*** made the decision as to whether a customer's due diligence information checked out.[102] While sales personnel were trained to look for red flags and were tasked with collecting due diligence information from customers and then providing that information to CSRA, their role in compliance ended there.[103] CSRA, utilizing both the information collected by the sales force and the metrics available through ABDC's ongoing due diligence, made decisions about whether (from a compliance perspective) to service a customer, whether to raise or lower a customer's threshold, and whether to cut off a customer.[104] Simply put, there was no conflict of interest.

II. Plaintiffs' Public Nuisance Claims Fail As A Matter Of Law Because They Amount To Impermissible Efforts To Enforce The Controlled Substances Act

Throughout this litigation, Plaintiffs have repeatedly invoked the federal Controlled Substances Act. Plaintiffs' closing arguments and their oppositions to Defendants' Rule 52(c) motions confirm that Plaintiffs' liability theory (both as to duty and breach) hinges on the CSA. Plaintiffs say that the CSA is the measuring stick for assessing Defendants' conduct and then say that Defendants engaged in wrongful conduct (either unreasonable or unlawful conduct) precisely

[102] 5/19 Tr. at 179:12-180:25 (Perry).

[103] *Id.*

[104] *Id.*

because they allegedly violated the CSA.[105] Thus, it could not be any clearer that Plaintiffs are seeking to enforce the CSA through their public nuisance claims.

Putting aside that Plaintiffs did not prove any violations of the CSA,[106] there is a profound legal problem with Plaintiffs' liability theory—indeed, it is barred as a matter of law. Allowing the imposition of public nuisance liability predicated on alleged CSA violations would directly conflict with United States Supreme Court precedent and the settled legal principle that there may be no indirect private enforcement of a federal statute when Congress has not expressed an intent to allow private enforcement.

As ABDC explained in its opening brief, violations of the federal CSA cannot provide the basis for a state law public nuisance claim. That is because United States Supreme Court precedent forbids imposition of tort liability based on violations of a statute like the CSA, for which Congress

[105] *See, e.g.*, 7/27 Tr. at 27:18-28:12 (Plaintiffs' closing argument) (asserting that the answer to the question, "[d]o the defendants owe a duty to maintain control," can be answered by looking to the CSA.); 7/27 Tr. at 31:17-34:4 (Plaintiffs' closing argument) (asserting that the answer to the question "[w]as the conduct unreasonable" can be assessed by determining whether the "defendants unreasonably failed to maintain effective controls against diversion" and "did the defendants fail to design and operate an effective Suspicious Order Monitoring System," noting "obligation under the law to look at these series of transactions and identify orders of unusual size, frequency or deviation from a normal pattern.); Tr. 7/28 at 150:15-17 (Plaintiffs' rebuttal argument) (stating: "This is a component of their job, to watch for, to monitor – design, monitor, and block orders that are suspicious."); Tr. 7/28 at 149-150 (Plaintiffs' rebuttal argument) (stating: "What they are, they're active participants charged by the United States Code and the Code of Federal Regulations to be responsible for the control valve."); Pl.'s Opp.to ABDC Br. at 38 (Section IV: "The Evidence Shows That ABDC's Distribution Of Opioids Into Cabell-Huntington Violated The CSA And The Requirement That ABDC Provide "Effective Controls" Against Diversion") Pl.'s Opp.to ABDC Br. at 44 (Section IV.B: "The Evidence Relating to ABDC's Diversion Control Program Establishes Unreasonable Conduct"; all argument related to CSA); Pl.'s Opp.to ABDC Br. at 45 (Section IV.C: ABDC's Conduct Was Unreasonable Because It Violated The CSA"); 7/1 Tr. at 90:23, 96:1-98-3, 106:22-107:3 (Plaintiffs' argument on Rule 52(c) motions) (describing duty and breach in terms of CSA).

[106] The reasons why the evidence does not prove a violation of the CSA is explained throughout ABDC's opening brief and in this reply brief.

had not authorized private enforcement.[107] Only Congress can authorize a private lawsuit for violations of a federal statute. *See Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) ("Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress."); *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 118 (2011) ("Recognition of any private right of action for violating a federal statute … must ultimately rest on congressional intent to provide a private remedy.") (internal quotation marks, citation, and alteration omitted).[108]

Congress did not confer a private right of action for violations of the CSA. Instead, it granted the exclusive authority to enforce the statute's comprehensive regulatory scheme to the United States Attorney General who, in turn, delegated that enforcement authority to the DEA. *See* DEA, *Practitioner's Manual, An Informational Outline of the Controlled Substances Act* (2006 ed); *Smith v. Hickenlooper*, 164 F. Supp. 3d 1286, 1290 (D. Colo. 2010) ("according to its plain terms, the CSA is a statute enforceable ***only*** by the [United States] Attorney General and, by delegation, the Department of Justice.") (emphasis added) (internal alterations omitted) (citing *Schneller v. Crozer Chester Med. Ctr.*, 387 F. App'x 289, 293 (3d Cir. 2010)).

And it's not just that the State cannot ***directly*** enforce the CSA, it also cannot ***indirectly*** enforce the statute through a state law claim based on alleged violations of the statute. The

[107] While Plaintiffs have not mentioned the WVCSA, it is worth noting that they cannot prove their public nuisance claims based on violations of that statute either. *See* ABDC's Mov. Br. at 38-41.

[108] A federal statute may be privately enforced only if Congress intended to create both (1) a right, not just a benefit, for a particular class of people; and (2) a private remedy. *Alexander*, 532 U.S. at 286; *see also Gonzaga Univ. v. Doe*, 536 U.S. 273, 283-85 (2002). Congressional intent is the touchstone with respect to both direct enforcement of a federal statute and indirect enforcement of the statute via another provision of law. Either way, Congress' intent is "determinative" and the statute itself is the beginning and end of the search for congressional intent. *Alexander*, 532 U.S. at 286. "Statutes that focus on the person regulated rather than the individuals protected create no implication of an intent to confer rights on a particular class of persons." *Id.* at 289 (internal quotation marks and citations omitted); *Gonzaga*, 536 U.S. at 284 n.3 ("where a statute does not include … explicit 'right- or duty- creating language,' we rarely impute to Congress an intent to create a private right of action").

Supreme Court has instructed that a state law cause of action may not be used as a vehicle to indirectly enforce a federal statute where Congress has not authorized private enforcement. When Congress has not conferred a private right of action and instead has delegated the authority to enforce a statute exclusively to the United States Attorney General, no one else can enforce the statute indirectly through a cause of action based on violations of the statute. *Astra*, 563 U.S. at 118. This bar on indirect enforcement holds even if private lawsuits might encourage compliance with a federal statute. *See Alexander*, 532 U.S. at 286-87; *Astra*, 563 U.S. at 121. "[I]t frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law" because "no legislation pursues its purposes at all costs." *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987); *see also Alexander*, 532 U.S. at 286-87 (in the absence of congressional intent, courts may not authorize private enforcement "no matter how desirable that might be as a policy matter, or how compatible with the statute").

Plaintiffs argue that they do not seek to enforce the CSA because their claim is one for public nuisance, stating that "[h]ad ABDC and the other Defendants ***merely*** violated the CSA and not thereby created a nuisance or otherwise violated parallel common-law duties, Plaintiffs would have no claim."[109] But that is to concede the dispositive point—Plaintiffs' claim ***depends*** on proving a violation of the CSA. A federal statute with no private right of action cannot be the linchpin for a state-law claim. Adoption of Plaintiffs' position would upend settled law. A plaintiff using a state-law claim to end run a federal statute's lack of a private right of action always could say that their claim is based on something more than a violation of the federal statute.

[109] Pl.'s Opp.to ABDC Br. at 45 (emphasis added). In a similar (misguided) vein, Plaintiffs argue, "Plaintiffs are not suing Defendants, directly or indirectly, for violating the CSA. They are suing Defendants for having created a public nuisance." Pl.'s Opp.to ABDC Br. at 47.

Plaintiffs' gambit is not new. Just as Plaintiffs say that Defendants' alleged violations of the CSA resulted in a public nuisance entitling them to state law remedies, the plaintiffs in *Astra* contended that the defendant's violation of a federal statute resulted a ***breach of contract*** entitling them to ***remedies under state contract law***. *Astra,* 563 U.S. at 116-17. The Supreme Court rejected this argument, explaining that a suit to enforce the contract was still "in essence a suit to enforce the statute itself" and "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if [litigants] could overcome that obstacle by suing to enforce the contract's ceiling-price obligations instead." *Id.* at 118.

Plaintiffs' assertion that *Astra* stands only for the "anodyne proposition, not in dispute here, that private rights of action under federal statutes must be created by Congress"[110] ignores entirely what *Astra* says and what Defendants have argued based on that precedent. Because Plaintiffs try to avoid the broad admonitions the Supreme Court set forth in *Astra*, a few more words on the Supreme Court's opinion in that case are in order.

In *Astra*, public hospitals and community health centers sued a drug manufacturer alleging that it charged prices higher than permitted under the federal Public Health Services Act, § 340B, 42 U.S.C. § 256b. *Astra*, 563 U.S. at 113. The manufacturer had opted into the § 340B program by contracting with the federal government to supply pharmaceuticals to the health centers at prices determined by a statutory formula. *Id.* The health centers—which conceded that there was no private right of action under § 340B—sued on a state law contract theory, alleging "that the manufacturers charged more than the § 340B ceiling price." *Id.* at 118. Because § 340B determined the "contract" price, the Supreme Court held that the plaintiff health centers were attempting by the "breach-of-contract" claim to indirectly enforce the provisions of the statute. *Id.*

[110] Pl.'s Opp.to ABDC Br. at 47 n.223

at 118-19. And because health centers may not sue under the statute, the court explained that "it would make scant sense to allow them to sue on a form contract implementing the statute, setting out terms identical to those contained in the statute." *Id.* at 114. The contract claim was "in essence a suit to enforce the statute itself." *Id.* ("Though labeled differently, suits to enforce § 340B and suits to enforce PPAs are in substance one and the same. Their treatment, therefore, must be the same, no matter the clothing in which [the plaintiffs] dress their claims.") (citing *Tenet v. Doe*, 544 U.S. 1, 8 (2005)).

The same goes here for the same reasons. An examination of the CSA's text and structure shows that Congress did not intend for the CSA to be privately enforced. In the CSA, Congress enacted a comprehensive regulatory scheme and granted the DOJ (and, in turn, DEA) remedial and regulatory powers to ensure compliance with the CSA and address CSA violations. As the Supreme Court has put it, "[i]n view of these elaborate enforcement provisions it cannot be assumed that Congress intended to authorize by implication additional judicial remedies for private citizens suing under" the federal statute. *Middlesex Cnty. Sewerage Authority v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 14 (1981).

It is noteworthy that Congress sought to strike an important balance in the CSA. The statute expressly recognizes that controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). Yet, Congress also recognized, "[t]he illegal importation ... and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the America people." *Id.* § 801(2). Accordingly, Congress designed the CSA not only to "prevent the[] misuse" of controlled substances, ***but also*** to "foster the beneficial use of those medications." *Gonzalez v. Raich*, 545 U.S. 1, 24 (2005). And that is why the DEA not only is

charged with investigating diversion, but also must "take[ ] just as seriously its obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound medical judgment of their physicians."[111]

A statute like this—one that seeks to strike a balance of sometimes competing considerations—is exactly the type of statute that is better suited for enforcement by regulators, not through private lawsuits. Allowing indirect private enforcement of statutes like these frustrates Congress' judgment to permit only agency enforcement. For example, the Supreme Court recognized in *Astra* that allowing individual private suits, "[f]ar from assisting" the administrative agency "would undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis," because they "could spawn a multitude of dispersed and uncoordinated lawsuits." *Astra*, 563 U.S. at 120. This result was to be avoided—even though the Department of Health and Human Services could not meet its enforcement burden. *Id.* at 119-20. Despite evidence of insufficient enforcement resources, the Court declined to infringe on Congress' policymaking function. It was enough simply to note that "Congress did not respond to the reports of inadequate … enforcement by inviting [health centers] to launch lawsuits in district courts across the country." *Id.* at 121.

The concern about individual lawsuits impeding agency judgments is particularly apt here. Plaintiffs' entire case is an exercise in trying to substitute their and their experts' judgment for DEA's judgment. For example, overwhelming evidence shows that DEA approved and endorsed ABDC's SOM programs, that DEA has never questioned the thresholds Defendants have utilized, and that DEA has never questioned the volume of prescription opioids shipped to Cabell and

[111] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52716, 52719-20 (Sept. 6, 2006); *see also* 6/8 Tr. at 199:5-203:18 (Rannazzisi); 6/9 Tr. at 87:7-11 (Rannazzisi).

Huntington. Yet, in the face of this evidence, Plaintiffs seek to substitute their judgment for DEA's and contend that Defendants' SOM programs were insufficient, Defendants' thresholds were too high, Defendants shipped too many opioids into Cabell and Huntington, and Defendants should have flagged and declined to ship more than 90% of the orders placed by Cabell and Huntington customers. This lawsuit, therefore, interferes profoundly with Congress' determination that the CSA should be administered by DEA alone—not through civil actions.

Yet, Plaintiffs go on to question what it means for a nuisance claim to be predicated on unlawful conduct "if the only plaintiffs that could seek relief from the nuisance were those otherwise entitled to enforce the underlying statute."[112] The answer is not complicated. To begin with, the CSA is not left without someone to enforce it—that is what DEA does.[113] And while others on whom Congress did not confer authority to enforce a federal statute—like Plaintiffs here—cannot base a state law nuisance claim on violations of the statute, that does not mean that those plaintiffs cannot base a nuisance claim based on different conduct. Plaintiffs' assertion that they are specifically entitled to sue for abatement of a nuisance[114] is misdirection. It is one thing to sue for abatement of a nuisance. It is another thing to premise that suit on a violation of a federal statute that lacks a private right of action.

Plaintiffs also suggest that *Astra's* holdings do not apply to them because they are government entities. But there is no support for that proposition. As ABDC has explained—and

[112] Pl.'s Opp.to ABDC Br. at 46.

[113] Indeed, during closing argument, this Court noted the importance of the regulatory framework that leaves enforcement to the DEA. 7/28 Tr. at 143:8-9 (Plaintiffs' counsel: "But the point of the matter is, is that there has been a recognition in the United States for a significant period of time that if we don't control narcotics then they will get out into the black market." The Court: "That's what the DEA is all about, isn't it?"); *see also* 7/28 Tr. at 142:22-23 (referencing current "regulatory framework").

[114] *Id.*

as controlling law provides—it is up to Congress to determine whether a statute may be enforced through a lawsuit or whether it may be enforced by the ***federal government*** alone. And, here, Congress has determined that the CSA should be enforced by the DEA alone. Plaintiffs' status as political subdivisions of the State of West Virginia does not confer upon them enforcement authority where Congress has not provided it.

In the end, because a claim based on violations of a federal statute "is in essence a suit to enforce the statute itself [,]" *Astra*, 563 U.S. at 118, allowing such a claim would authorize private enforcement of the statute—which would contravene Congress' judgments about who may enforce the CSA. *See id.* ("The absence of a private right [of action] to enforce the statutory ... obligations would be rendered meaningless if [plaintiffs] could overcome that obstacle by suing to enforce the contract's ... obligations instead."); *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994) (explaining that permitting a plaintiff to enforce statutory or regulatory duties through common law negligence "would, in effect, be permitting a private cause of action" under the statute).

CONCLUSION

Judgment on partial findings pursuant to Rule 52(c) should be entered in ABDC's favor because Plaintiffs did not meet their burden to prove wrongful conduct, which is an essential element of a public nuisance claim.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2021, the forgoing ***AmerisourceBergen Drug Corporation's Reply Memorandum In Support of Motion For Judgment Under Rule 52(c) Based On Plaintiffs' Failure To Prove Culpable Conduct*** was sent to Counsel for the Plaintiffs and Defendants using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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